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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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BURNS DOANE SWECKER & MATHIS L L P			HILL, MYRON G	
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ALEXANDRIA, VA 22313-1404			1648	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,502

Applicant(s)

FLUGEL ET AL.

Examiner

Myron G. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1- 16 is/are pending in the application.
- 4a) Of the above claim(s) 13- 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1- 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>C/18/01 11/6/01</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's election with traverse of Group I in paper 24 March 2004 is acknowledged. The traversal is on the ground(s) that the other groups are similar and any nominal additional search burden is outweighed by benefit to public of not having to obtain multiple patent to study applicants' invention, that the MPEP states that if the search can be accomplished without serious burden, all inventions should be examined, that the PCT was not held to lack unity, and that if there are conflicts between PCT and the PTO in lack of unity, the PCT rules apply citing *Caterpillar* (231 USPQ 590). This is not found persuasive because restriction was based on lack of unity and Applicant did not argue or present evidence as to what was improper about the lack of unity as applied with art. The USPTO is not held to what the ISA does. The burden is not a factor considered under lack of unity. The citation *Caterpillar* (231 USPQ 590) does not provide a similar fact situation and does not apply in this instance because it sets forth the situation wherein a National Stage Application was subjected to restriction based on USPTO practice and this was not held proper. The instant application has been shown to lack unity and therefore may be restricted into the different inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claims 13- 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

This action is on claims 1- 12.

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Sequence Requirements

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on as follows:

The specification does not contain sequence identifiers (SEQ ID#s) in all locations where sequences are disclosed, see at least Example 1.

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with both these requirements in the time period set forth in this Office Action will be held non-responsive.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 fails to further limit the invention of claim 1 because it recites "a foamy virus" and claim 1 requires in the first DNA sequence at least part of a FeFV reverse transcript.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not enabling for the said claims. The specification does not provide a repeatable method for obtaining a full length FeFV clone, and it does not appear to be readily available material. Deposit of the full length FeFV clone would satisfy the enablement requirements of 35 U.S.C. 112. Applicant's deposit information in the specification does not indicate the extent of public availability.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and **that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent**, would satisfy the deposit requirements. See 37 CFR 1.808.

Claims 1, 2, 4- 6, and 8-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vector comprising a full length clone of FeFV, does not reasonably provide enablement for vectors containing only a portion of the genome. The specification does not enable any person skilled in the art

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to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The instant claims are evaluated for scope of enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The claims are drawn to a FeFV viral vector that only contain a portion of the genome. For this rejection, the claims are interpreted as to contain nothing more than the recited elements.

In the instant case, other than the full length clone, the instant specification is not-enabled for such vectors that contain only a portion of the viral genome. Winkler *et al.* is cited as evidence of the state of the prior art in that it teaches the full length clone of FeFV and provides detailed comparison of important features of FeFV as related to other retroviruses. The state of the prior art relating to the making and using other retroviral vectors is high and is an area of active research. Spuma viruses including human and feline (FeFV) are believed not to cause disease in host animals and thus are good candidates for vectors.

The specification provides only guidance and direction to the fact that the vector sequence is taken from Winkler *et al.* (see at least page 5, line 28 and page 10).

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However, there is no evidence or guidance or directions as to the specific minimum sequence required or the function of specific sequences less than the full length clone as a vector. The enabling disclosure is clearly not commensurate in scope with these claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Clearly there is lack of guidance directing a skilled artisan to practice the instantly claimed methods. Without specific guidance or direction and /or working examples, one of ordinary skill in the art would not be able to reproducibly practice the entire scope of the invention as claimed, without undue experimentation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1- 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler *et al.* (Journal of Virology 1997, Vol. 71, pages 6727- 6741, from IDS) and Schmidt *et al.* (Virology 1995, Vol. 210, pages 167- 178, from IDS).

The invention is drawn to an retroviral vector comprising at least part of a reverse transcript of the FeFV genome. For this rejection, the claims are interpreted to contain more than the minimum recited elements because of the comprising language.

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Winkler *et al.* teach the same clone as used in the invention (Example I) and teach that it can be used to make vectors for targeted gene delivery (page 6740, column 1, top).

Winkler *et al.* do not make a retroviral vector.

Schmidt *et al.* teach replication competent foamy virus vectors that express foreign genes (abstract).

One of ordinary skill in the art at the time of invention would know about construction of retroviral vectors and could use the detailed information in Winkler *et al.* to construct FeFV vectors. It is well known in the art that retroviral vectors are used to express or deliver foreign genes. One of ordinary skill in the art would be motivated to make a FeFV retroviral vector to study foamy viruses in vivo as taught by Winkler *et al.* (page 6727, last paragraph of introduction). Knowing the full length sequence and having the partial clones of Winkler *et al.* it would have been obvious to make a plasmid that contains a full length proviral clone. It appears that the sequence of the clone of claim 8 which is taught in Example 1 that results in the deposited pFeFV-7 is the same cloned viral sequence as the fully described clone of Winkler *et al.*

Thus, it would have been prima facie obvious to make a FeFV retroviral vector with the clone of Winkler *et al.* with the expectation of success knowing that vectors can be made from foamy viruses as taught by Schmidt *et al.*

Conclusion

No claim is allowed.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Myron G. Hill
Patent Examiner
25 May 2004



JAMES HOUSEL 6/1/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600